Author’s response to reviews

Title: Development of a tailored strategy to improve postpartum hemorrhage guideline adherence

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Author’s response to reviews:

Dear Editor-in-chief

Thank you for the opportunity to revise our manuscript after the useful reviews of the four reviewers, Ashraf Fawzy Nabhan, Gregory Halle Ekane, Mavis Schorn and Sadaf Khan. We are pleased to get an opportunity for adapting the protocol for publication.

On the following pages you will find the answers on the remarks the reviewers provided. In the manuscript the adaptations are indicated by track changes.

As stated in the answer to one of the questions posed by the reviewers adding the tools as a supplement would add to the manuscript’s clarity, we are currently translating the tools from Dutch to English. The tools were created in Dutch as they are made for the Dutch setting. As soon as the supplements are available we will send them through the manuscript submission site.

We hope you will accept our manuscript for publication in BMC Pregnancy and Childbirth.
Reviewer reports and our response

Ashraf Fawzy Ibrahim Mohamed Nabhan, M.D. (Reviewer 1): Thank you for the effort in conducting this work and for submitting this manuscript. I agree with the investigators that evidence-based guidelines are not optimally adhered to, leading to substandard care and a gap between evidence-based medicine and clinical application. This is why this work and similar work is important.

I have few yet critical queries:

1. In the methods section

A. International literature was searched: Please detail the methods of search activities for example was it a systematic comprehensive search? was there any language or date restrictions? How were the publications screened?

We did not perform a full systematic comprehensive search. The language restriction were English papers only, and no date restriction was performed. The publications were screened by reading the title and abstract.

B. Kindly do not discuss the content of the retrieved literature in the methods eg., Actual care was particularly not in accordance with guidelines with regard to the high risk identification and documentation of policy for PPH on the outpatient clinic and during labor, vital signs monitoring, and the different steps in the management of PPH.
We have discussed the issue of where to place the results of the actual care study in the article among all authors extensively. As the results of the actual care study are not results of this article (this study is currently submitted for publication, and therefore not available for referencing yet) we were in doubt where the best place for this part is. We have decided to change it from the methods section to the results section ‘setting’.

C. The authors only provided general terms for their additional search in phase 2. A clear line by line search activities should be provided as a supplement for all search activities.

Unfortunately, a clear line by line search activity has not been saved at the time of the search.

2. In the results section: authors should not discuss their findings. Discussion should be in the discussion section.

In the results section we describe the conclusions of the literature we have found and describe the tools we have made by stating the purpose and goals of the tools and how they are to be used. We believe that this is not a discussion but a description of the tools. If there are parts the reviewer sees are discussing the results we kindly ask which parts and we will gladly adjust the text and place the parts identified as discussion to the discussion section.


The study of Chaillet et al is a systematic review on effectiveness of implementation strategies in the field of obstetrics. After reading their article, one knows what type of tools are generally effective within obstetrics, however you do not know how to create such a tailored implementation strategy. This is what our study adds to their review. It described the process of the development of such a strategy. We believe that merely copying a strategy into a different setting will not be as effective as developing an implementation strategy tailored to setting. A conclusion Chaillet et al state as well, that most effective strategies are based on a prospective analyze of the current care. How one can use such a prospective analysis to decide on tools to use in the strategy and how to create a strategy is described in our article.

4. I am not sure what exactly is the tailored strategy developed. Figure 2 needs to be clearly explained and detailed in the narration. This is the core of the whole work.
In the results section Phase two: content detailing and tool development we discuss the strategy and its contents extensively on page 10, 11 and the top of page 12. We have adjusted to the legend of the figure to indicate where in the narration a full description can be found.

5. Finally, it is true that this work would be meaningful when tested regarding the feasibility and effectiveness of the proposed strategy in the clinical practice.

We have recently finished collecting and analyzing the data. We hope to report on the feasibility and give an indication on effectiveness soon.

Halle-Ekane Edie Gregory, MD (Reviewer 2):

GOOD INNOVATIVE WELL WRITTEN MANUSCRIPT WILL DEFINITELY PLAY AN IMPORTANT ROLE IN REDUCING MORBIDITY AND MORTALITY ASSOCIATED WITH PPH IN HIGH AND LOW RESOURCE COUNTRIES SEE TRACKED MANUSCRIPT FOR SOME CONCERNS.

Dr Gregory Halle Ekane

Thanks you very much for the feedback. We have adjusted the abstract regarding your remarks.

Mavis Schorn (Reviewer 3): The authors are commended for addressing a significant health issue for childbearing women. This paper's purpose is to describe the development of an implementation strategy for a high resource obstetric setting to improve guideline adherence regarding PPH. Coordinating efforts to manage postpartum hemorrhage is key to minimizing related morbidity and mortality, so finding a way to improve PPH risk identification, intervention, and follow up is important. In addition, engaging childbearing women in tools designed for their benefit is a strength of this paper.

Following are a few suggestions for consideration to enhance the value of this manuscript:

1. Background: Although the incidence of PPH is reported as increasing, there may be reasons other than a true increase in hemorrhage. For example, the reported increase may also be due to a significant increase in attention to PPH. In some locations, there have been changes in
the threshold of blood loss that then increase the rate. Substandard care for women who experienced 1500cc or more blood loss was cited in a review paper published over 15 years old. Are there any current references that support the theoretical basis for this work? The introduction/background should address literature regarding current guidelines, or lack thereof, in treating PPH to support why additional work in guideline development is needed. Linking guidelines development to implementation and then to adherence could be made stronger.

There has indeed more current literature on suboptimal care in PPH care. We have added those references to the background. The article of Chaillet et al (Obstet & Gynaec, 2006) reviews implementation strategies in Obstetrics. They conclude that implementations strategies are important for optimal guideline adherences. In our FLUXIM project, of which this article is part of, we are trying to prove that mere spread does not lead to optimal adherence, and that the development of the strategy leads to better adherence and decrease in the PPH incidence.

2. Methods: The description of the phases and the contents challenging to follow and tie back to the purpose. The following suggestions may increase the clarity: 1. The headings of the phases could be more reflective and clear as to the content of each phase. For example Phase one: Strategy selection does not tell the reader what to expect. The text also does not tell the reader initially as to what to expect in this section. We have adjusted the headings to the content of the paragraphs and made sure all paragraphs started with a summarizing sentences of that paragraph. The description of the search strategy was not specific. In phase two - clarifying what type of tools were being developed first, followed by a description about how each were developed would increase clarity. We believe that stating what type of tools were being developed is part of the results, and is described there. There were references to guidelines in the literature. The authors might consider if a table comparing the guidelines would be useful. This paper does not provide the final guidelines, nor does it provide the specifics of other available guidelines. We have added the references of the used guidelines in the article. Phase three: the process for feedback did not follow any particular framework. There were only physicians among the expert panels when other healthcare team members will likely participate prenatally, during labor/birth, and postpartum follow up - such as midwives, nurses, and possibly mental health counselors or others. It is true that for the development of the strategy only physicians and experts of implementation science have participated in the expert team. Other health care professionals would have added to the team. For the feasibility trial we will incorporate a process evaluation of the strategy and the tools, in which all health care professionals and patients are requested to provide feedback on various topics such as lay-ouy, workability, and effectiveness. The patient material should be evaluated from a health literacy and reading level perspective. We have requested the patients to review the material on readability. Patients of all educational levels were incorporated.
3. Results: The steps described discussed a process of development in contrast to the statement that a strategy to improve adherence to guidelines was created. A guideline does not ensure adherence, and link between the two was not make clear. It is also unclear what the tool are. Even if the tools cannot be shared yet, a general description of each tool and their components is needed (more detail). I am curious about the time out including the laboring women at the end of stage 1. If women have regional anesthesia, this might be practical. If they are unmedicated or using nitrous, this might not be a very practical plan - which then decreases adherence to the proposed guidelines. The checklist for PPH treatment is said to guide professionals through consecutive treatment options, etc.; however, few professional groups were represented in the creation. In addition, it is unclear on what basis a checklist for treatment was created since the evidence about "consecutive treatment options" based on comparative effectiveness is not strong (http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?productid=1918&pageaction=displayproduct)

We have tried to clarify the description of the tools. However we understand that supplying an example of the tools would be the ideal situation. Therefore we are currently busy to translate the tools from Dutch to English. Once we have those available, we will add these to the manuscript as a supplement.

The timing of the time-out is left up to the labor-ward team. For a primiparous women this would be close to fully dilatation, for a multiparous women this would perhaps be at 7 cm dilatation. The most important aspect is that the team that is most likely to be present during the second and third stage of the delivery performs the time-out. This is all explained in the presentation we gave to the team. As a small preview: in the feasibility trial this time-out was considered the most valuable tool and the execution of it (and timing) posed no issue. However this is a result of the feasibility trial and can therefore be not part of this article.

Concerning the consecutive actions: we have tried to create a strategy to improve implementation of the guideline that was in use at that moment. At that time, those consecutive actions were considered best evidence. The study did not review the content of the guideline with the latest evidence. The strategy is made in such a way that it is content independent, so that with an update of the guideline the tools merely have to be updated on content for them to still be usable.

4. Discussion: there is earlier reference to a treatment checklist, but in the discussion there is discussion about a PPH preventative care bundle. These terms/tools need clarification.
The description in the results of the care bundle was unclear, which lead to an difficulty understanding the difference. We have adjusted this in both the results section as the first paragraph in the discussion to clarify the two.

Thank you for the opportunity to review this paper. The work in reducing poor maternal outcomes related to PPH is important. The goal of determining whether there is an improvement in maternal outcomes related to the tools developed will certainly be of interest to those providing maternal care.

Sadaf Khan (Reviewer 4): Methods: For phase I the authors reference a literature review and expert consult for their strategy selection, but I was unable to identify the process with which this review was finalized (whether the literature was predominantly high/low resource settings) and how the experts chose the highest priority barriers.

We have added information about the literature selection, however as mentioned in response to earlier feedback we, unfortunately, cannot provide a line by line search strategy.

We have a description of the selection of the barriers and facilitators: [The barriers and facilitators from the professional level chosen for the implementation strategy were those mentioned by at least three out of the four focus groups, and feasible to incorporate in our strategy. These barriers were discussed among the authors to determine which barriers were most likely to supply the greatest gain for improvement and were feasible to include. The same selection criteria were applied to the facilitators. On the patient level, through consensus among the authors, barriers and facilitators were identified as eligible for the strategy.]

The references 10, 11 which seem to allude to the final are from a single author (peer reviewed publication and dissertation) and the FLUXIM study (ref 9) seems to be the key sources for this information. I would recommend the authors define their processes more clearly and whether this framework is based principally on the FLUXIM trial's findings or how it was ensured the gaps (and therefore the resulting framework) was made more applicable to other high resource settings.

As stated in the setting section of the methods, the findings of the FLUXIM trial are the primary basis of the development of the strategy. Foremost we wanted to create an implementation strategy for the Dutch PPH guideline. Using the literature search we find out what in general are effective tools in the field of obstetrics. As argued in the discussion (paragraph 5) we believe that the framework is applicable in similar (other high resource countries) settings as the barriers
seem universal, and as the literature are concerning all high resource settings and not just the Dutch situation.

IO would also suggest the authors add more detail around the expert reviewer's feedback on their strategy and tools. Did the recommendations for improvement of the website come from patients or the expert reviewers?

As stated in the section ‘phase three’ of the results, the expert panel did not have any suggestions for improvement. The expert panel was satisfied on the items we requested: the accuracy of the medical content, clinical usability and controlling for inconsistencies with the current best evidence care as stated in the Dutch PPH guideline.

All the suggestions for improvements of the website came from the patients. We have adjusted the section ‘phase three’ of the results to clarify this.

Conclusions: It may be worthwhile highlighting in the discussion section previous attempts to address the issue in the Netherlands, why these did not work and what gaps this particular framework will fill that were not addressed by previous efforts. A feasibility study would be the next step but before a feasibility study is undertaken, is there feedback from and buy-in into this concept from professional associations?

As far as it is known by the authors, there have not been previous attempts made to improve the implementation of the guideline other than the mere dissemination of the guideline. Discussing this in the discussion section will therefore not be possible. The Dutch professional association has not been involved in the feasibility trial, however they were enthusiastic about the preliminary results we provided to the ZonMW who gave the grant to perform the FLUXIM trial. As a result of the feasibility trial, the tools of the strategy have been incorporated into the updated version of the PPH guideline and the association has supported the FLUXIM group to educate all hospitals with labor wards in the Netherlands about the strategy and how to incorporate it in the daily hospital care.

Language: I would suggest some proofing and editing (though not major) to improve readability. However the paper needs to have a better flow. It was hard for me to track the process and assessment in the way the article is currently drafted.

We hope that clarifying the section headings and the opening line of the section improves the flow of the article. When drafting the manuscript we have extensively discussed the flow and order of the article among the team and consulted other researchers for their opinion. After
gathering all opinions the current lay-out of the article was considered the clearest, however we do understand that the article remains difficult to interpret for both obstetricians or implementation scientist as the topic combines these two field.